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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,342	02/28/2002	Michael Douglas Spears	SPER-100A	2921

28304 7590 04/07/2004

JEAN M. MACHELEDT
501 SKYSAIL LANE
SUITE B100
FORT COLLINS, CO 80525-3133

EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 04/07/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,342	SPEARS, MICHAEL DOUGLAS	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8 and 9* is/are allowed.

6)☒ Claim(s) *1-7 and 12-20* is/are rejected.

7)☒ Claim(s) *10 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Eggers (USPN 5,807,392).

Regarding claims 1 and 14, Eggers discloses a resistive heat cutting and coagulating surgical instrument comprising a radio frequency source (14) electrically connected to an

impedance matching circuit (149) comprising a tuning element in the form of a capacitor (162) and an inductive element in the form of a transformer (150), wherein the inductive element is electrically connected to a conductive cutting tip (24) via a switch contact area located on or encased in the device handle /housing (22) (see reference to a switch on the handle 22 in col. 7, lines 18-30), it should be noted that inherently electrical current flows through the housing, the impedance matching circuit and the switch contact area, see col. 6, line 49 through col. 7, line 67and col. 12, line 25 through col. 13, line 62 and figures1-4. The step of treating soft-tissue is disclosed in the abstract and col. 1-6 where Eggers discusses the cutting and hemostasis of tissue (interpreted as including soft-tissue by the examiner).

Regarding claims 15 and 16, Eggers discloses an inductive element in the form of a transformer. Transformers have a primary winding, a secondary winding and a core that couples the windings to each other electromagnetically. Additionally, an impedance matching device that conducts electromagnetic energy does so with the presence of eddy currents when conducting the energy through tissue during cutting. Also Eggers discloses the provision of power to the cutting tip 24 via a cable (16) that electrically connected to the tuning element and it is inherent that the electromagnetic cutting device disclosed by Eggers conducts energy through its cutting tip, see col. 6, line 49 through col. 7, line 67 and col. 12, line 25 through col. 13, line 62 and figures1-4.

Claims 1 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Denen et al. (USPN 5,445,635).

Regarding claim 1 and 14, Denen et al. disclose a resistively-heated surgical instrument and method comprising a radio frequency source (20) electrically connected to an impedance matching circuit (40) comprising a tuning element in the form of a capacitor (15 of Figure 7) and an inductive element in the form of a transformer (50 of figure 7), wherein the inductive element is electrically connected to a conductive cutting tip (15 of figure 1) via a switch contact area located on or encased in the device handle /housing (14) (see reference to a switch on the handle 14 in col. 13, lines 37 through col. 14, line 17), it should be noted that inherently electrical current flows through the housing, the impedance matching circuit and the switch contact area, see col. 5-14 and figures1, 2 and 7. The step of treating soft-tissue is disclosed in the abstract and col. 1-14 in general and col. 7, lines 33-59 specifically (where "moist tissue" is interpreted as including soft-tissue by the examiner).

Regarding claims 15 and 16, Denen et al. disclose an inductive element in the form of a step-up transformer (50). Transformers have a primary winding, a secondary winding and a core made from a ferromagnetic material, see col. 11, lines 39-54 and figures 5 and 6. Additionally, an impedance matching device that conducts electromagnetic energy does so with the presence of eddy currents when conducting the energy through tissue during cutting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers (USPN 5,807,392) in view of Yamanashi et al. (USPN 6,059,781).

Regarding claim 2, Eggers further discloses a probe tip (24) that is releasably engaged with the probe housing via a release mechanism (127, 128 and 138), see col. 12 and figures 1-5. Eggers discloses the claimed invention except for explicitly reciting that the housing has an electrically insulative layer and/or providing an electrical amplifier. It is extremely well known in the art to provide an electrosurgical instrument/device with a handle/housing having an electrically insulating layer in order to prevent electrical shock to the operator or other unintended electrical conductor. Yamanashi et al disclose a RF generator source (44) connected to an impedance matching circuit (52) comprising an inductive element ("tuning coil" 30) and a conductive cutting tip (24, 26, 38, 40 and/or 43), see col. 4, lines 6-65 and figures 1-7. Yamanashi et al. also disclose that the

instrument is used to surgically treat tissue through contact, see abstract. Yamanashi et al. disclose a transformer (30) and teach providing an electrically insulated housing in order to prevent electrical shock, see col. 4, lines 29-33 and figures 5 and 7. Applicant discloses that it is well known in the art to include an electrical amplifier ("RF Amplifier" in figure 1 and labeled as "Prior Art") in order to enhance the delivery of energy to the load. Additionally, Yamanashi et al. also teach the use of an amplifier (48) in order to provide electromagnetic fields which in turn induces eddy currents in the tissue, see col. 1, lines 50-67, and col. 5 and 6 and figure 6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Eggers, as is well known in the art and shown by Yamanashi et al., to provide an electrosurgical instrument/device with a handle/housing with an electrically insulating layer in order to prevent electrical shock to the operator or other unintended electrical conductor, and as is well known in the art and shown by Applicant and Yamanashi et al. to use of an amplifier in order to provide electromagnetic fields which in turn induces eddy currents in the tissue.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denen et al. (USPN 5,445,635) in view of Esty et al. (USPN 4,032,738) and still in further view of Rydell (USPN 5,810,809).

Regarding claim 2 and 3, Denen et al. disclose the claimed invention including an amplifier (65) except for explicitly disclosing a metal handle/housing having an

insulative layer and that the tip is releasably engagable. It is well known in the art to provide a wide variety of handles that provide a rigid protective casing/housing for electrical components in the form of a hollow metal handle and to further layer the hollow metal handle with an insulative layer to prevent electrical shock. Rydell discloses an electrosurgical instrument and teaches that it is known in the art to provide a "hollow metal handle" in order to contain various electrical/mechanical components, see col. 1, lines 13-43. Furthermore, it is extremely well known in the art to provide electrosurgical instruments with electrical insulation on the handle in order to prevent electrical shock to the operator. The examiner takes official notice of the claimed electrically insulating layer on the housing. Furthermore, the examiner interprets insulative layer as inherently comprising a dielectric material. Esty et al. disclose an electrosurgical instrument and teach the provision of placing a printed circuit board (31), containing the impedance matching circuitry, within the hand-held housing (10) of the instrument in order to provide low cost elements and techniques as well as a more compact arrangement, see col. 5, lines 29-62. Esty et al. also teach the use of providing the hand-held housing with an electrical switch (11 and 12 or 54 and 55) in order to provide convenient manual use by the surgeon, see abstract and col. 2, lines 16-60. Esty et al. do not disclose the switch connected between the inductive element and the conductive cutting tip, however as is well known in the art facilitates the conduction or non-conduction of treatment energy via the closing or opening of the electrical circuit by the switch. Esty et al. teach the use of proving the housing with a "replaceable chuck" (15) such that a wide variety of tips can be used with one instrument, see col. 2, lines 16-42 and figure 1. Therefore at the time of

the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Denen et al., as is well known in the art and disclosed by Rydell, to provide a wide variety of handles that provide a rigid protective casing/housing for electrical components in the form of a hollow metal handle, and as is further well known in the art and taken official notice of, to provide electrosurgical instruments with electrical insulation on the handle in order to prevent electrical shock to the operator.

Claims 4, 6, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denen et al. (USPN 5,445,635) in view of Esty et al. (USPN 4,032,738) and still in further view of Rydell (USPN 5,810,809) as applied to claim 2 above, and further in view of Carlson et al., "Electrical Engineering: Concepts and Applications", 2nd Ed., Addison and Wesley 1990, pages 149-186.

Regarding claims 4 and 12, Denen et al. in view of Esty et al. and still in further view of Rydell disclose the claimed invention. With the teaching of the "replaceable chuck" by Esty et al. as mentioned in regards to claim 2 above, the second end of said tip is inherently engaged with a release mechanism. However, Denen et al. in view of Esty et al. and still in further view of Rydell fail to disclose the capacitor is connected to a center-tapped transformer. It is also well known in the art to use the features of "step-up", "step-down" and center-tapped or multiply-tapped transforming depending on the desired voltage ratio and/or terminals. The flexibility, variability and rearrangement of capacitors, inductors and transformers is well known by one of ordinary skill in the art

and demonstrated by the university level text by Carlson et al., who present or teach the use of resistors, capacitors, inductors and transformers when dealing with alternating current energy transmission. From this text, it should be noted that issues of a) using capacitive and inductive elements for impedance matching means, b) obtaining specific primary-to-secondary voltage ratios is well known, and c) using center-tapped or multiply-tapped transformers for various output voltage or current are known very well. Therefore it would be obvious to one of ordinary skill in the art to modify the invention of Denen et al. in view of Esty et al. and still in further view of Rydell, as is well known in the art and demonstrated and shown by Carlson et al., to connect the capacitor to a center-tapped transformer in order to obtain specific primary-to-secondary voltage ratios and use center-tapped or multiply-tapped transformers to obtain various output voltage or current.

Regarding claim 6, Denen et al. in view of Esty et al. and still in further view of Rydell disclose the claimed invention. Specifically Denen et al. disclose a step-up transformer having a primary winding to secondary winding ratio of 8:1. At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use a wide range of primary to secondary windings ratio because Applicant has not disclose that a 2:1 ratio provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any number of ratios for step-up transformer windings because the electrical power generators provide variable power

delivery which in turns can deliver a large range power to the load. Furthermore, pending a statement of criticality the recited primary to secondary windings ratio is considered to be an obvious design choice over the ranges of Denen et al. and not patentably distinct thereover.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denen et al. (USPN 5,445,635) in view of Esty et al. (USPN 4,032,738) and still in further view of Rydell (USPN 5,810,809) and further in view of Carlson et al., "Electrical Engineering: Concepts and Applications", 2nd Ed., Addison and Wesley 1990, pages 149-186. as applied to claim 2 above, and still further in view of Anderson et al. (USPN 4,607,161).

Regarding claims 5 and, Denen et al. in view of Esty et al. in view of Rydell in view of Carlson et al. disclose the claimed invention except for explicitly reciting "directing light waves through an optical fiber to said switch-contact area comprising a photodetector." It should be noted that a hollow metal handle disclosed in Rydell, serves as EM shielding as is well known from Gauss's Law. Anderson et al. disclose a fiber optic switch system and teach the use of an optical switch (16), an optical fiber (15) and a photodetector (44). The motivations for this optical switch provision are well known in the art and include avoiding electrical point bounce, electrical contact resistance, electrical short, mechanical failure as well as expense. Additionally, Anderson not only teaches the use of optical switches, it also teaches the advantages of optical switches over electrical or mechanical switches. Finally, Anderson et al. is directed to fiber optics and it discloses that fiber

optics is widely used in the medical field, see col. 1, lines 12-20. Additionally, the recited frequency range is interpreted as intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Denen et al. in view of Esty et al. in view of Rydell in view of Carlson et al., as taught by Anderson et al. and as is well known in the art, to use of an optical switch, an optical fiber and a photodetector in order to avoid electrical point bounce, electrical contact resistance, electrical short, mechanical failure and expense inherently involved with electrical/mechanical switches.

Claims 7, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers (USPN 5,807,392) in view of Esty et al. (USPN 4,032,738).

Regarding claims 7 and 17, Eggers discloses the claimed invention except for explicitly reciting a switch-contact area of a switch comprising non-conductive protuberance extending through an aperture in a casing for said switch and/or "directing a sufficient force against a non-conductive switch-protuberance having at least one surface in contact with a spring-engaged conductive pathway within a switch casing, such that said conductive pathway makes contact with said switch-contact area." Eggers does not disclose the specific structure of the switch contact area, but does specify that the switch

contact area is provided on the housing/handle. Esty et al. disclose an electrosurgical instrument and teach the provision of placing a printed circuit board (31) within the hand-held housing (10) of the instrument in order to provide low cost elements and techniques as well as a more compact arrangement, see col. 5, lines 29-62. Esty et al. also teach the use of providing the hand-held housing with an electrical switch (11 and 12 or 54 and 55) in order to provide convenient manual use by the surgeon, see abstract and col. 2, lines 16-60. The electrical switch disclosed by Esty et al. comprises a non-conductive switch-protuberance (22 and 29) extending through an aperture in a casing and having at least one surface in contact with a spring-engaged conductive pathway (30) within a switch casing (36), such that said conductive pathway makes contact with said switch-contact area ("the upwardly arcuate configuration of these flexible devices permits downward movement of plunger 29 so as to momentarily deform deflectable metal dome 30 thus completing a switch function in association with electrical contact points on circuit board 31," see col. 4, lines 33-38). Providing sufficient force to the switch-protuberance such that said conductive-pathway makes contact with said switch-contact area is inherent and is the very nature of operation of electrical switches with spring-engaged conductive pathways. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Eggers, as taught by Esty et al., to a non-conductive switch-protuberance having at least one surface in contact with a spring-engaged conductive pathway within a switch casing, such that said conductive pathway makes contact with said switch-contact area.

Regarding claim 18, Eggers further discloses a releasably connectable cable-release assembly comprising a cable (16) having a connectors (48, 50, 52 and 54). One end of the cable (16) is connected to the treatment device by connectors (52 and 54), while the other end is attached to the generator (14) by connectors (48 and 50). The cable release assembly is comprised of the connectors (52 and 54) at the distal end of the cable (16) and opposing engaging connectors (125 and 126) located in the proximal end of the handle or handle portion (22), see col. 7 and 8, col. 12, lines 25-41and col. 13, lines 10-26 and figures 1, 3 and 4. The steps engaging a cable to the cable-release assembly or mechanism to connect the RF source is inherent to the cable/cable release assembly or mechanism disclosed.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers (USPN 5,807,392) in view of Anderson et al. (USPN 4,607,161).

Regarding claim 19, Eggers discloses the claimed invention except for explicitly reciting "directing light waves through an optical fiber to said switch-contact area comprising a photodetector." Anderson et al. disclose a fiber optic switch system and teach the use of an optical switch (16), an optical fiber (15) and a photodetector (44). The motivations for this optical switch provision are well known in the art and include avoiding electrical point bounce, electrical contact resistance, electrical short, mechanical failure as well as expense. Additionally, Anderson not only teaches the use of optical switches , it also teaches the advantages of optical switches over electrical or mechanical switches.

Finally, Anderson et al. is directed to fiber optics and it discloses that fiber optics is widely used in the medical field, see col. 1, lines 12-20. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Eggers, as taught by Anderson et al. and as is well known in the art, to use of an optical switch, an optical fiber and a photodetector in order to avoid electrical point bounce, electrical contact resistance, electrical short, mechanical failure and expense inherently involved with electrical/mechanical switches.

Regarding claim 20, Eggers in view of Anderson et al. disclose the claimed invention. In regards to the conduction of current through the tuning element, the inductive element, the impedance matching circuit, the tip and the biological tissue or material, the device and method of Eggers inherently involve this conducting current. Also the step of making contact with the tissue is inherent. Eddy currents are inherently present within the soft electrically-conductive material when impedance matching instruments are used to electrically treat the soft electrically-conductive material.

Allowable Subject Matter

Claims 8 and 9 are allowed.

Claims 10 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

The three declarations under 37 CFR 1.132 filed as paper # 10 on 1/22/2004, paper #11 on 1/22/2004 and paper #12 on 1/22/2004 are sufficient to overcome the rejection of claims 1-7 and 12-20 based upon Yamanashi et al. (USPN 6,059,781) in view of Esty et al. (USPN 4,032,738) applied under 35 U.S.C. 103. As Applicant has so thoroughly pointed out in the amendment and the three declarations under 37 CFR 1.132, there is no disclosure, implication, suggestion and/or teaching specifically disclosed in Yamanashi et al. (USPN 6,059,781) or Esty et al. (USPN 4,032,738) to place the impedance matching circuit on the printed circuit board.

The examiner has previously interpreted the teaching of Esty et al. (upon Yamanashi et al.) to use a printed circuit board to inherently allow the placement of the impedance matching circuit on the printed circuit board. In the interest of providing the best available prior art in order to illustrate traditional and well known features in the art, the examiner has withdrawn the previous rejections and provided prior art (Eggers (USPN 5,807,392) which was previously provided and Denen et al. (USPN 5,445,635) which is a new prior art reference) that disclose a

resistively-heated electrosurgical instrument that comprise both an impedance matching circuit and an energy activation switch in the handle. The examiner hopes that these two references will serve to clearly demonstrate that it is well known in the art to provide resistively-heated electrosurgical instruments with both an impedance matching circuit and an energy activation switch in the handle.

Based on the new grounds for rejection, the arguments to the previously made rejections are now rendered moot.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. A.R.
April 5, 2004

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER